

Serial No. 09/856,571

Atty. Docket No. Mo 6341/LeA 33 270

Claims (Attorney Docket No. Mo 6341/LeA 33 270)

1. (Original) Semi-hydrochloride of 8-cyano-1-cyclopropyl-7-(1S,6S-2,8-diazabicyclo[4.3.0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.
2. (Currently amended) Semi-hydrochloride of 8-cyano-1-cyclopropyl-7-(1S,6S-2,8-diazabicyclo[4.3.0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid (CCDC semihydrochloride), having an X-ray powder diffractogram with the following reflection signals (2 theta) of high and medium intensity[.]

θ (2 Theta)
5.86
6.90
7.26
8.98
9.35
10.13
10.68
10.97
12.41
13.67
14.57
14.89
15.73
16.07
16.47
16.87
17.78
18.91
19.81
20.04
20.62
20.75
20.93
21.46
21.74
22.92
25.36
25.71
26.98
27.58
28.24
30.61

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3. (Currently amended) Semi-hydrochloride of 8-cyano-1-cyclopropyl-7-(1S,6S-2,8-diazabicyclo-[4.3.0]nonan-8-yl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid (CCDC semihydrochloride), having X-ray powder diffractogram with the following reflection signals (2 theta) of high and medium intensity[[]]

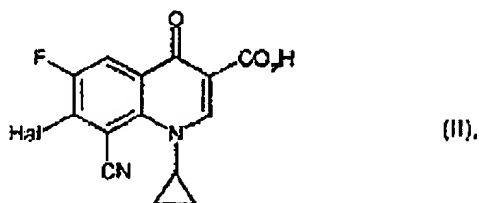
2 θ (2 Theta)
5.86
6.90
7.26
8.98
9.35
10.13
10.68
10.97
12.41
13.67
14.57
14.89
15.73
16.07
16.47
16.87
17.78
18.91
19.81
20.04
20.62
20.75
20.93
21.46
21.74
22.92
25.36
25.71
26.98
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28.24
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and a melting point, determined by DTA, of from 278°C to 280°C.

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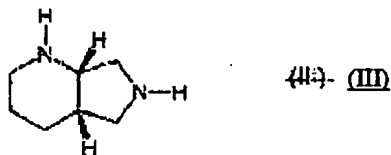
4. (Cancelled).
5. (Currently amended) A process for preparing CCDC semihydrochloride according to Claim 1, comprising reacting 7-halogeno-8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid of the formula (II)



in which

Hal ~~represents fluorine or~~ represents chlorine

and (1S,6S)-2,8-diazabicyclo[4.3.0]nonane of the formula (III)



in the presence of a base in one of the following diluents or diluent mixtures:

- a) aliphatic alcohols selected from the group consisting of butanol, isobutanol, 2-butanol, tert-butanol, and 1-pentanol,
- b) mixture of aliphatic alcohols selected from the group consisting of propanol, isopropanol, butanol, isobutanol, 2-butanol, tert-butanol, and 1-pentanol with N-methylpyrrolidone,
- c) mixture of propanol and N,N-dimethylformamide,

or

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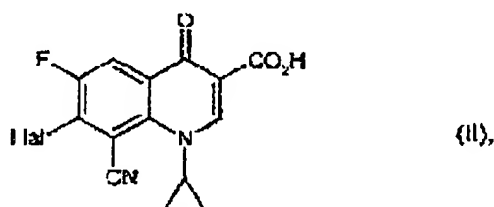
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- d) mixture of ethanol with N-methyl-pyrrolidone with added tripropylamine, tributylamine, N-ethylmorpholine, N-propylmorpholine and/or N-butylmorpholine base.
6. (Previously amended) A process for preparing CCDC semihydrochloride according to Claim 5, wherein the diluent used is an aliphatic alcohol selected from the group consisting of butanol, isobutanol, 2-butanol, tert-butanol, and 1-pentanol or that an aliphatic alcohol selected from the group consisting of ethanol, propanol, isopropanol, butanol, isobutanol, 2-butanol, tert-butanol, and 1-pentanol is used as component of a diluent mixture.
 7. (Previously amended) A process for preparing CCDC semihydrochloride according to Claim 5, wherein if an aliphatic alcohol selected from the group consisting of propanol, isopropanol, butanol, isobutanol, 2-butanol, tert-butanol, and 1-pentanol is used as component of a diluent mixture, N-methyl-pyrrolidone is simultaneously employed as a further diluent in a ratio of from 1 to 1 to 3 to 1.
 8. (Previously amended) Process for preparing CCDC semihydrochloride according to Claim 6, wherein if propanol is used as component of a diluent mixture, N,N-dimethylformamide is simultaneously employed as further diluent in a ratio of from 1 to 1 to 3 to 1.
 9. (Currently amended) A pharmaceutical composition comprising, in addition to ~~eustomary~~ pharmaceutically acceptable auxiliaries and excipients, CCDC semihydrochloride according to Claim 1.
 10. (Currently amended) A method of preparing a pharmaceutical composition comprising formulating combining a CCDC semihydrochloride according to Claim 1 with one or more pharmaceutically acceptable auxiliaries and excipients.
 11. (Currently amended) A process for treating bacteria comprising applying thereto to a human or animal an antibacterial composition containing CCDC semihydrochloride as defined in Claim 1.

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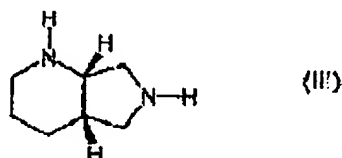
12. (Currently amended) CCDC semihydrochloride according to Claim 2, obtainable by reacting 7-halogeno-8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-3-quinoline-carboxylic acid of the formula (II)



in which

Hal represents ~~fluorine or~~ chlorine,

and (1S,6S)-2,8-diazabicyclo[4.3.0]nonane of the formula (III)



optionally in the presence of a base, in one of the following diluents or diluent mixtures:

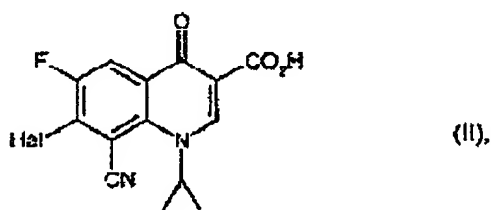
- a) aliphatic alcohols having at least four carbons,
- b) mixture of aliphatic alcohols having at least three carbon atoms with N-methylpyrrolidone,
- c) mixture of propanol and N,N-dimethylformamide,

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or

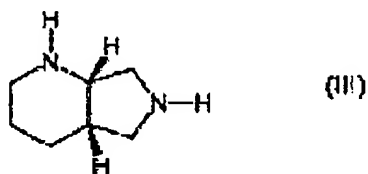
- d) mixture of ethanol with N-methyl-pyrrolidone with added tripropylamine, tributylamine, N-ethylmorpholine, N-propylmorphine and/or N-butylmorphine base.
13. (Currently amended) A process for preparing a CCDC semihydrochloride as defined in Claim 2, wherein 7-halogeno-8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid of the formula (II)



in which

Hal ~~represents fluorine or~~ represents chlorine

and (1S, 6S)-2,8-diazabicyclo[4.3.0]nonane of the formula (III)



are reacted in the presence of a base in one of the following diluents or diluent mixtures:

- a) aliphatic alcohols having at least four carbon atoms,
- b) mixture of aliphatic alcohols having at least three carbon atoms with N-

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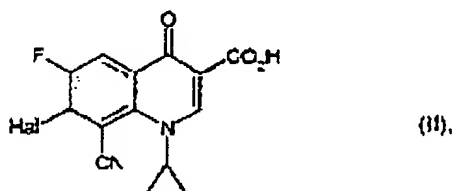
methylpyrrolidone,

c) mixture of propanol and N,N-dimethylformamide,

or

d) mixture of ethanol with N-methyl-pyrrolidone with added tripropylamine, tributylamine, N-ethylmorpholine, N-propylmorpholine and/or N-butylmorpholine base.

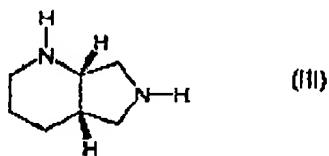
14. (Currently amended) A process for preparing a CCDC semihydrochloride as defined in Claim 3, wherein 7-halogeno-8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid of the formula (II)



in which

Hal ~~represents fluorine or~~ represents chlorine

and (1S,6S)-2,8-diazabicyclo[4.3.0]nonane of the formula (III)



are reacted in the presence of a base in one of the following diluents or diluent mixtures:

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- a) aliphatic alcohols having at least four carbon atoms,
 - b) mixture of aliphatic alcohols having at least three carbon atoms with N-methylpyrrolidone,
 - c) mixture of propanol and N,N-dimethylformamide,
 - or
 - d) mixture of ethanol with N-methyl-pyrrolidone with added tripropylamine, tributylamine, N-ethylmorpholine, N-propylmorpholine and/or N-butylmorpholine base.
15. (Cancelled).
16. (Currently amended) A pharmaceutical composition comprising, in addition to ~~eustomary~~ pharmaceutically acceptable auxiliaries and excipients, CCDC semihydrochloride according to Claim 2.
17. (Currently amended) A pharmaceutical composition comprising, in addition to ~~eustomary~~ pharmaceutically acceptable auxiliaries and excipients, CCDC semihydrochloride according to Claim 3.
18. (Cancelled).
19. (Currently amended) A method of preparing a pharmaceutical composition comprising ~~formulating combining a~~ CCDC semihydrochloride as defined in Claim 2 with one or more pharmaceutically acceptable auxiliaries and excipients.
20. (Currently amended) A method of preparing a pharmaceutical composition comprising ~~formulating combining a~~ CCDC semihydrochloride as defined in Claim 2 3 with one or more pharmaceutically acceptable auxiliaries and excipients.
21. (Cancelled).

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22. (Currently amended) A process for treating bacteria comprising applying ~~thereto~~ to a human or animal an antibacterial composition containing CCDC semihydrochloride as defined in Claim 2.
23. (Currently amended) A process for treating bacteria comprising applying ~~thereto~~ to a human or animal an antibacterial composition containing CCDC semihydrochloride as defined in Claim 3.
24. (Cancelled).